

CLAIMS

What is claimed is:

1. A method for chemical treatment of biological tissue, comprising the steps of:
 - 5 (a) providing a quantity of biological tissue which contains connective tissue protein; and,
 - (b) contacting the biological tissue with a solution under oxidizing conditions for sufficient time to impart enhanced stability compared to traditional means of fixing connective tissue protein within the biological tissue.
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- 2: A method according to Claim 1 wherein the oxidizing conditions are provided in step (b) by heating the solution in the presence of oxygen.
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3. A method according to Claim 2 wherein the presence of oxygen is provided by ambient oxygen in the solution.
4. A method according to Claim 2 wherein at least some of the oxygen present is provided by allowing the solution to contact atmospheric air, oxygen or an oxygen-containing gas solution.
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5. A method according to Claim 2 wherein at least some of the oxygen present is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.
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6. A method according to Claim 1 wherein the oxidizing conditions are provided in step (b) by combining an oxidizing agent with the solution in the presence of oxygen.
7. A method according to Claim 6 wherein the oxidizing agent is selected from the group of oxidizing agents consisting of a peroxide, a compound containing peroxide, a hydrogen peroxide, a periodate, a compound containing periodate, sodium periodate, a
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diisocyanate compound, a halogen, a compound containing halogen, n-bromosuccinimide, a permanganate, a compound containing permanganate, ozone, a compound containing ozone, chromic acid, sulfuric chloride, a sulfoxide, a selenoxide, and combinations thereof.

5 8. A method according to Claim 6 wherein the presence of oxygen is provided by ambient oxygen in the solution.

10 9. A method according to Claim 6 wherein at least some of the oxygen present is provided by allowing the solution-oxidizing agent mixture to contact atmospheric air, oxygen or an oxygen-containing gas mixture.

15 10. A method according to Claim 6 wherein at least some of the oxygen present is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.

20 11. A method according to Claim 1 wherein the oxidizing conditions are provided in step (b) by irradiating the solution in the presence of oxygen.

25 12. A method according to Claim 11 wherein the solution is irradiated by a type of radiation energy selected from the group of alpha ionizing radiation, beta ionizing radiation, ultraviolet radiation, electron beam radiation, gamma rays, and combinations thereof.

13. A method according to Claim 11 wherein the presence of oxygen is provided by ambient oxygen in the solution.

25 14. A method according to Claim 11 wherein at least some of the oxygen present is provided by allowing the solution to contact atmospheric air, oxygen or an oxygen-containing gas mixture.

15. A method according to Claim 11 wherein at least some of the oxygen present is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.

16. A method according to Claim 1 wherein the solution is flowing.

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17. A method according to Claim 16 wherein the flowing of the solution is effected by placing the solution and the tissue in a container, wherein the solution is heated and circulated through the container.

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18. A method according to Claim 1, wherein step (b) comprises the steps of:
placing the tissue in a solution containing 0.2-2.0 % glutaraldehyde;
maintaining the glutaraldehyde solution at 25-70 °C for a period of
0.5-60 days; and,
removing the tissue from the glutaraldehyde solution.

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19. A method according to Claim 18 wherein the solution has a glutaraldehyde concentration of about 0.625%.

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20. A method according to Claim 19 wherein the 0.625% glutaraldehyde solution is maintained at about 45-55 °C for a period of between about 7 and 14 days.

21. A method according to ~~Claim 1~~ wherein the solution is a fixative.

22. A method according to Claim 21 wherein fixative is glutaraldehyde.

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23. A method according to Claim 21 wherein fixative is Denacol.

24. A method according to Claim 1 wherein the solution is peroxide.

25. A bioprosthesis comprising tissue that has been prepared by a method comprising the steps of:

(a) providing a quantity of biological tissue which contains connective tissue protein; and,

5 (b) contacting the biological tissue with a solution under oxidizing conditions for sufficient time to result in crosslinking of connective tissue protein within the biological tissue.

26. A bioprosthesis according to Claim 25 wherein the oxidizing conditions in
10 step (b) are provided by heating the solution in the presence of oxygen.

27. A bioprosthesis according to Claim 25 wherein the presence of oxygen in step (b) is provided by ambient oxygen in the solution.

15 28. A bioprosthesis according to Claim 25 wherein at least some of the oxygen present is provided by allowing the solution to contact atmospheric air, oxygen or an oxygen-containing gas solution.

20 29. A bioprosthesis according to Claim 25 wherein at least some of the oxygen present in step (b) is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.

25 30. A bioprosthesis according to Claim 25 wherein the oxidizing conditions are provided in step (b) by combining an oxidizing agent with the solution in the presence of oxygen.

30 31. A bioprosthesis according to Claim 30 wherein the oxidizing agent is selected from the group of oxidizing agents consisting of a peroxide, a compound containing peroxide, hydrogen peroxide, a periodate, a compound containing periodate, sodium periodate, a diisocyanate compound, a halogen, a compound containing halogen, n-

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bromosuccinimide, a permanganate, a compound containing permanganate, ozone, a compound containing ozone, chromic acid, sulfonyl chloride, a sulfoxide, a selenoxide, and combinations thereof.

5 32. A bioprostheses according to Claim 30 wherein the presence of oxygen is provided by ambient oxygen in the solution-oxidizing agent mixture.

10 33. A bioprostheses according to Claim 30 wherein at least some of the oxygen present is provided by allowing the solution-oxidizing agent mixture to contact atmospheric air, oxygen or an oxygen-containing gas mixture.

15 34. A bioprostheses according to Claim 30 wherein at least some of the oxygen present is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.

35. A bioprostheses according to Claim 25 wherein the oxidizing conditions are provided in step (b) by irradiating the solution in the presence of oxygen.

20 36. A bioprostheses according to Claim 35 wherein the solution is irradiated by a type of radiation energy selected from the group consisting of: alpha ionizing radiation, beta ionizing radiation, ultraviolet radiation, electron beam radiation, gamma rays, and combinations thereof.

25 37. A bioprostheses according to Claim 35 wherein the presence of oxygen is provided by ambient oxygen in the solution.

30 38. A bioprostheses according to Claim 35 wherein at least some of the oxygen present is provided by allowing the solution to contact atmospheric air, oxygen or an oxygen-containing gas mixture.

39. A bioprosthesis according to Claim 35 wherein at least some of the oxygen present is provided by bubbling oxygen or an oxygen-containing gas mixture through the solution.

5 40. A bioprostheses according to Claim 25 wherein the solution is flowing.

41. A bioprosthesis according to Claim 40 wherein the flowing of the solution is effected by placing the solution and the tissue in a fixation container, wherein the solution is heated and circulated through the container.

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